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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,167	10/17/2001	Chunhua Yan	CL001303	3910

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EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 11/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

FILE COPY

Office Action Summary	Application No.	Applicant(s)	
	09/978,167	YAN ET AL.	
	Examiner	Art Unit	
	David J Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *August 12, 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,8,9 and 24-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,8,9 and 24-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

[1] Claims 4, 8-9, and 24-37 are pending in the application.

[2] Applicant's cancellation of claims 1-3, 5-7, and 10-23, amendment to claims 4 and 8, and addition of claims 24-37 in Paper No. 6, filed August 12, 2003, is acknowledged.

[3] Applicant's election without traverse of Group III, original claims 4-6, 8-11, and 22-23, drawn to an isolated nucleic acid encoding SEQ ID NO:2 in Paper No. 6 is acknowledged.

Sequence Compliance

[4] This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825; applicants' attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). To be in compliance, applicant is required to identify all amino acid sequences of at least 4 L-amino acids and at least 10 nucleotides by a sequence identifier, i.e., "SEQ ID NO:". The specification discloses sequences that have not been identified by a sequence identifier (see Figures 2A, 2B, and 3BB-3FF). If these sequences have not been disclosed in the computer readable form of the sequence listing and the paper copy thereof, applicant must provide a computer readable form copy of the "Sequence

Listing" including these sequences, a paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification, and a statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d).

Specification/Informalities

[5] The attempt to incorporate subject matter into this application by reference to a hyperlink embedded in the specification (see particularly page 9, lines 26 and 30) is improper. Incorporation of subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP 608.01 regarding hyperlinks in the specification and 608.01(p), paragraph I regarding incorporation by reference.

[6] The "Description of the Figure Sheets" section of the specification (page 4) fails to properly identify the drawings. Each of the drawings is identified in the specification as Figure 1, 2, or 3. However, the actual drawings are listed as Figures 1A, 1B, 2A, 2B, etc. It is suggested that applicant amend the specification to properly identify the drawings in the specification.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

[7] Claims 4, 8-9, and 24-37 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or well-established utility. The claims are drawn to isolated polynucleotides encoding SEQ ID NO:2 or a variant of SEQ ID NO:2 with isoleucine at position 281, host cells containing vectors encoding SEQ ID NO:2 or a variant of SEQ ID NO:2 with isoleucine at position 281, and a process for producing a polypeptide using said host cells.

The claimed polynucleotide has no substantial utility as further experimentation is required to establish its "real world" use as explained in detail below. Applicants state, "[t]he present invention is based in part on the identification of amino acid sequences of a novel human nephronectin splice form". The identification of the polypeptide of SEQ ID NO:2 as a nephronectin splice form, although not expressly stated by applicant, appears to be based on 84-87% amino acid sequence identity with mouse nephronectins as shown in Figures 2C-2E. It appears that mouse nephronectin is involved in the development of the embryonic kidney by association with integrin $\alpha 8\beta 1$and is potentially involved in the development of other organs as well (see Brandenberger et al. *J Cell Biol* 154:447-458 and page 3 of the instant specification). Based on this evidence, applicant asserts, "novel human nephronectin splice forms are particularly useful as therapeutic targets for treating developmental disorders" (page 3 of the specification). However, the specification fails to provide the necessary guidance such that one of ordinary skill in the art could obtain the desired therapeutic effect, i.e., treating developmental disorders. Thus, further experimentation is required in order to identify those agents that may be useful in targeting nephronectin and the type of

developmental disorders that may be treated with such. Furthermore, Brandenberger et al. (supra) acknowledge that the mechanism by which nephronectin and $\alpha 8\beta 1$ mediate kidney development is not well understand by stating, "[w]hatever the mechanism, further investigations using [nephronectin] should advance our understanding of the puzzling function of $\alpha 8\beta 1$ in kidney development" (page 456, right column, middle). In view of this teaching one of ordinary skill in the art clearly would not be able to predict the effect(s) of an effector, i.e., either an activator or inhibitor, of the polypeptide encoded by SEQ ID NO:1 or 3 or the recited variant and it is unclear as to what practical benefit is derived by the public from the identification of such an effector. As stated above, Brandenberger et al. (supra) teach nephronectin is expressed in the embryonic kidney, however, there is no indication that mRNA encoding SEQ ID NO:2 is expressed in the embryonic kidney (see Figure 1B) and neither the specification nor the prior art teach those additional tissues – if any – that require nephronectin in their development. While the specification shows that mRNA encoding SEQ ID NO:2 is expressed in various tissues, it is unclear as to which – if any – of these tissues nephronectin plays a developmental role. It is also noted that in the absence of empirical data to verify the function of the polypeptide of SEQ ID NO:2 or the recited variant, it is unclear as to whether these polypeptides have *any* biological activity. It is known in the art that splice variants can be non-functional due to alteration(s) in the encoding sequence and without functional characterization of the polypeptide of SEQ ID NO:2 it is just as likely that this polypeptide is non-functional. Thus, one of ordinary skill in the art would recognize that further experimentation is required in order to establish a "real world" use

for the polynucleotide of SEQ ID NO:1 and 3 and the recited variants thereof. This type of utility is not considered a "substantial utility". See e.g., *Brenner v. Manson,* 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966). The specification must teach a skilled artisan how to use what is claimed and not merely provide a blueprint for further experimentation in order for an artisan to identify a use for the claimed invention. Here the claimed polynucleotides are suitable only for additional research.

Regarding a specific utility, applicant asserts various utilities for the claimed polynucleotides (pages 29-35 of the instant specification). These utilities include use as probes, primers, chemical intermediates, and biological assays. However, none of these asserted utilities is a specific utility for the claimed polynucleotides. The asserted utilities also include use in disease treatment and diagnosis. However, the specification fails to disclose a nexus between the claimed polynucleotides and a specific disease state such that the polynucleotide is useful as a diagnostic or in the treatment of a disease state or condition. Therefore, the asserted utilities are not specific to the claimed polynucleotides and are instead general utilities that would be applicable to the broad class of polynucleotides.

For the reasons stated above, the claimed polynucleotide has no specific and substantial utility.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[8] Claims 25 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 25 and 27 are indefinite in the recitation of "having a nucleotide sequence consisting of". The scope of claimed polynucleotides is unclear because the claims recite the terms "having" and "consisting of" as explained in detail below. The term "having", according to MPEP § 2111.03, can be interpreted as open or closed claim language and is typically interpreted as open claim language in claims drawn to nucleic acid sequences. The term "consisting of", according to MPEP § 2111.03, is closed claim language. Therefore, because the claims recite both terms, it is unclear as to the scope of claimed polynucleotides. It is noted that if the term "having" in claim 25 were interpreted as using open claim language, claims 25 and 26 would be identical in scope and claim 26 would be a substantial duplicate of claim 25. In view of the duplicity of claims 25 and 26 (if the term "having" in claim 25 were interpreted as open language), the examiner has interpreted the term "having" in claims 25 and 27 as closed claim language and claims 25 and 27 have been essentially interpreted as "[a]n isolated polynucleotide consisting of SEQ ID NO:1" and "[a]n isolated polynucleotide consisting of SEQ ID NO:3", respectively. Because the term "having" is typically interpreted as open claim language in claims drawn to nucleic acid sequences, it is suggested that applicant clarify the scope of claimed polynucleotides by, for example, amending the term "having a nucleotide sequence consisting of" to "consisting of" in claims 25 and 27.

Conclusion

[9] Status of the claims:

- Claims 4, 8-9, and 24-37 are pending.
- Claims 4, 8-9, and 24-37 are rejected.
- No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:00 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (703) 746-5078. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman
Patent Examiner
Art Unit 1652

10-31-03

DAVID STEADMAN
PATENT EXAMINER